

Maryland Board of Pharmacy

Public Board Meeting

October 16, 2002

President Ades called the Public Session of the October 16, 2002 Board meeting to order at 9:15 a.m.

Attendance:

Commissioners Present: Stanton Ades, President; John Balch; Melvin Rubin; Ramona McCarthy-Hawkins; Raymond Love; W. Irving Lottier, Jr.; Jeanne Furman; Wayne Dyke and Rev. William Johnson

Absent: Donald Yee

Board Counsel: Paul Ballard, Assistant Attorney General; and Linda Bethman, Staff Attorney

Board Staff: James Slade, Legislative/Regulations Officer; Shirley Costley, Fiscal/Personnel Officer; Joan Lawrence, Public Education Officer; Deitra Gale, Compliance Specialist; Vladimir Konstantinov, Information and Technology Specialist and Sandra Hines, Secretary

Guests: Jason Noel, Pharm.D. (PEAC); Howard Schiff (MPhA); Charlene T. Hosley, Pharm.D. Candidate (MPhA); Kathryn Lavriha (Barr Labs); Jack Freedman (DDC)

Introduction

President Ades asked each guest to introduce him or herself.

Recusals

There were no recusals of members due to conflicts of interest.

Corrections and Approval of Minutes (09/18/02)

Page 1, under Guests: name should read, "Nathan Gruz."

Page 4, under Pharmacy Practice Committee, third paragraph, fourth sentence should read: "The Practice Committee felt that if..."

Page 4, under Pharmacy Practice Committee, third paragraph, fifth sentence should read: "Dr. Love stated that..."

Page 4, under Pharmacy Practice Committee, third paragraph, seventh sentence should read: "...anyone who charges needs to be aware..."

Page 4, under Long Term Care: first paragraph, second sentence should read: "will be attending the Task Force..."

Page 4, under Long Term Care: first paragraph, third sentence should read: "there is limited medication..."

Page 5, under Updated Inspection Forms, first sentence should read: "laptops to enter data."

Page 5, under Updated Inspection Forms, fifth sentence should read: "Division of Drug Control prior to inspection."

Page 6, under On-Line Renewal System, first sentence should read: "final stages and is anticipated..."

Page 6, under Security, first sentence should read: 15% in FY 2004 budgets..."

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Board Action

Dr. Love moved for acceptance of the September 18, 2002 public meeting minutes with corrections. The motion was seconded by Ms. Furman and passed by the Board.

President/Executive Committee Report

Bio-Terrorism Task Force

Pres. Ades reported that the "Pharmacist's Response to Bio-Terrorism Seminar" was held in Ocean City on October 5, 2002. The seminar was very well represented and was attended by 87 participants. The seminar contained the same agenda as the seminar held at the University of Maryland in Baltimore.

The next scheduled seminar will be held on October 19, 2002, in Cumberland. As of the date of the Board meeting, 50 people had registered to attend. Nearly 400 pharmacists have been trained. Only half of the pharmacists who registered to volunteer have been trained. Additional seminars in the DC area and another in Baltimore may be scheduled in the future.

Shortage of Pharmacists Update

Pres. Ades presented the preliminary report from the survey that was answered by 600 pharmacists around the State.

NABP Task Force Appointments

Pres. Ades reported that two Board members have been appointed to NABP's 2002-2003 Committee and Task Force Appointments: Ms. Furman was appointed to serve on the "Transition of Pharmacy Regulation From the Dispensing Process to Outcomes" Committee and Mr. Rubin was appointed to serve as an alternate for the "Committee on Law Enforcement/Legislation."

NABP District II Meeting

Pres. Ades reported that the NABP District II meeting will be held next week. Ms. Naesea, Mr. Rubin and Ms. Furman will represent the Board at the meeting.

Executive Director's Report

Staffing Update

Ms. Costley reported that the Board is still having a problem with filling the Clinical Pharmacist position. Ms. Naesea and DHMH Personnel Director have discussed rewriting the job description or creating a different title for this position.

Ms. Costley reported that the three Office Secretary III candidates interviewed by Ms. Naesea and Mr. Slade, declined the position for various reasons. She noted that the position was a lateral transfer for the candidates that were interviewed may have been used as leverage with their current job. DHMH Personnel is forwarding another list of eligible candidates to the Board.

Board Staff Retreat

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Ms. Costley presented the estimated costs and training availability for the staff training retreat. The Board is looking at three locations to have the retreat and corresponding with three training development programs that may be used to provide support at the retreat.

Legislative/Regulations Report

BoP Regulations Status Report #2

Mr. Slade reported that the first status of changes of reinstatement for the pharmacist became effective on October 14, 2002.

Mr. Slade presented a memorandum received from Ms. Mattie Simmons, Instructor, Health Occupations Students of America (HOSA). Ms. Simmons asked the Board to draft a letter of support for HOSA. Ms. Simmons's letter indicated that the State Department of Education wants to combine HOSA with the trade group VICA, to reduce the workload. HOSA prepares students specifically for health professions, where as VICA prepares students for trade professions. Mr. Slade will write a letter supporting HOSA for their program and what it represents.

PEAC (Pharmacists Education and Assistance Committee) – Update

Mr. Jason Noel reported on behalf of PEAC that they have 29 active cases, of which one is new and one case was discharged. Mr. Noel distributed the program outline for their Annual Conference/Seminar hosted by PEAC, on October 26th at the Maritime Institute. Ms. Lawrence and Ms. Furman will represent the Board at the Conference.

COMMITTEE REPORTS

Pharmacy Practice Committee

Dr. Love reported that the Committee met on October 2nd. He stated that the Committee discussed the correspondence received regarding the Collaborative Drug Therapy Management initial draft regulations. The Committee also developed an alternative fee structure. The correspondence received indicated that the \$500 application fee might be excessive. The Committee broke the fee down to \$250 to set-up an agreement and \$50 for the protocol fee. Dr. Love reported that the Committee spent most of the meeting time discussing how to respond to DTM comments and possible changes to the regulations based on suggestions from those who commented.

All changes proposed by the Practice Committee will need to be approved by BPQA before they are finalized. Mr. Slade stated that the Committee would present proposed changes to BPQA at the next Practice Medicine Committee meeting in December.

Questions

Dr. Love reported that the Board received a letter from Mr. Larry Siegal, Carroll County, regarding a series of questions on what pharmacist need to do regarding specific practices in hospital pharmacies such as dosage adjustment for anti-biotic, TPN, etc. Ms. Furman drafted a response letter summarizing the Committee's deliberations, indicating that after reviewing the Attorney General's opinion about hospital practices, the hospital pharmacy's decisions needed to be supported by specific criteria which in essences is a decision making tree. The pharmacist can not use excessive amounts of independent judgment, but should make clinical judgments through a decision-making process that relates to the specific criteria. Ms. Furman's response letter also advised Mr. Siegal that to the extent possible, they should be rather specific in the criteria and the protocols so that the decisions adhered to the Attorney General's opinion. Dr. Love

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thanked Ms. Furman for doing a nice job summarizing the wording for the response to the question from Carroll County.

Dr. Love stated that the Committee deliberated on the issue of when a physician calls a nurse in a long-term care facility and the nurse faxes an order to the pharmacy, whether it is a problem because the nurse is not an employee of the physician and therefore not *really* the agent of the physician.

Recommendations

Dr. Love presented to the Board that in the case that an RN in a long-term care facility receives an order from a physician for a prescription medication or a DEA scheduled medication, the RN may reduce the order to writing on the patient's chart as a verbal order and fax this order to the pharmacist. The pharmacist may then fill the order and under that circumstance, consider the RN as an agent of the prescriber. The Committee further recommended that the Board refer this matter to the Long-Term Care Task Force to insure that this is incorporated in their discussions of revisions of the Long-Term Care guidelines.

Board Action

Dr. Love moved on behalf of the Committee that the Board accept the Committee's recommendations with regards to RN transitions and physician's orders in the Long-Term Care Facilities. The motion was seconded by Ms. Furman and passed by the Board.

Long Term Care

Mr. Balch reported that the Task Force met on October 17th. Mr. Balch the Board to approve support of the Task Force's decision for a sub-committee to meet with the Office of Health Care Quality (OHCQ) to resolve some issues. The Task Force met with Ms. Lisa Condon to discuss the problems members had with Assisted Living. Mr. Balch suggested that the sub committee, meet with Ms. Condon, the Board of Nursing and Ms. Mary Hanover, OHCQ. Pres. Ades and Mr. Rubin will represent the Board at the meeting.

Board Action

Ms. Furman moved that the Board proceed with the approval of the Task Force decision. The motion was seconded by Dr. Love and passed by the Board.

Mr. Balch announced that the Beacon Institute is having a symposium on Assisted Living on October 23rd.

Licensing Committee

Mr. Dyke announced that this month was the first time that the Board did not have the monthly reciprocity meeting. The new process requires candidates to complete the State MPJE computerized testing exam, receive a 75% score or better and pass all competency components. Mr. Dyke stated that since it is not necessary to appear in person for the monthly meeting, the Board now depends on NABP to get the results of the MPJE testing to the Board. The Board will expect the results to arrive on a daily or weekly basis and once a month the Committee will compile the numbers of the candidate names and present the report to the Board at the monthly Board meetings.

Reciprocity

Mr. Dyke reported that since no reciprocity meeting was held October 15th there are no candidates to report and the Board has not received a notification from NABP yet.

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New Procedures for Reciprocity Candidates

Mr. Dyke reported that a Licensing Committee meeting was held on October 15th. The Committee reviewed and streamlined the reciprocity process. It was decided that the Board would become a “clearinghouse” and receive all initial paperwork from reciprocity candidates. The Board would then forward the paperwork to NABP. The Board will clarify information and perform background checks of the candidate in advance of NABP providing the information. Mr. Dyke indicated that the Board will forward the fees received to NABP and distribute the Law Books to the candidates.

Reciprocity – Reducing fees/Conference call

Mr. Dyke reported that Ms. Naesea conducted board members conference call the week previous to discuss equalizing any possible fee increases since a fee increase would discourage persons from reciprocating into Maryland. The fee would be reduced from \$250 to \$120. Mr. Slade reported that he is waiting for a response of the suggested reduced fee.

Lab Exam -Update

Mr. Dyke reported that the Wet Lab Exam was held on Tuesday, October 1st. He thanked everyone for proctoring and grading the exams. Seventy candidates participated and passed the examination. The next Wet Lab Exam, if necessary, will be held in January or February 2003.

Canadian Pharmacy

Mr. Rubin stated concerns about the Board’s decision to turn the information from the Canadian Pharmacy sending medication to Maryland over to the FDA to consider action. The MPhA’s Newsletter indicated that the “Board only decided to turn the information over to the FDA to consider action.” Mr. Rubin stated that there is a conception that the Board is not considering the safety of the citizens of Maryland and that it should go on record that the Board is concerned about the safety of the citizens of Maryland and that the Board is basically powerless to do anything prior to the FDA’s involvement. Members support this suggestion.

Disciplinary Committee

Mr. Rubin announced that Mr. Konstantinov is working with the Division of Drug Control on revising their Inspection Form. Mr. Konstantinov reported that the form is ready to be presented. The form will be tested in the field during the next three (3) months. The form will be fully operational by January 2003.

Response to Complainants

Ms. Gale reported that she met with Ms. Naesea to give her an update on complaints and investigations. From the results of that meeting, Ms. Naesea decided to draft a standard letter to the complainants explaining the delay in processing complaints. Ms. Gale presented the draft letter to the Board for approval. Mr. Rubin requested that the second sentence be removed from the first paragraph.

Board Action

Ms. McCarthy-Hawkins moved for acceptance of the letter with amendments. The motion was seconded by Ms. Furman and passed by the Board.

Backlog of Consumer Complaints

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Ms. Furman reported concerns about not addressing the consumer complaints in a timely manner. Ms. Furman suggested that in certain cases, the Board can comfortably close a case with the appropriate letter. Ms. Furman will assist Ms. Gale in answering some of the complaints by using the Medication Error Form to send out to the permit holder and the pharmacist.

Ms. Furman announced that the Disciplinary Committee meeting has been rescheduled for Thursday, November 7, 2002 at 9 a.m.

Maryland Patient Safety Coalition Report

Ms. Furman reported that the Maryland Patient Safety Coalition is winding down the bulk of the work. A synopsis of the draft regulations was distributed for review. Ms. Furman reported that the draft regulations can be found on the Department of Health and Mental Hygiene's web site under the Office of Health Care Quality. The regulations will require that the hospitals set-up a Patient Safety Program and a Patient Safety Coordinator. There are plans for the Maryland Patient Safety Center to be set-up at the University of Baltimore.

Technology and Automation Report

Status of IT Projects

Mr. Konstantinov reported that the MHCC will be unable to complete the Online Renewal System in time for usage by all establishments. The system will be made available for testing at selected locations only. MHCC is asking that the system be tested on a least 40% of the establishments' licensure database; this should include some chains, independent pharmacies, waivers, non-resident pharmacies and distributors. Mr. Rubin and Ms. James will solicit participation in the test and verify with Mr. Ballard that as long as the establishments' applications are in the system before December 1st, there will be no late fee.

Mr. Konstantinov reported that MHCC held a meeting on October 3rd. MHCC expects to complete their establishment system for Phase I testing in mid November. The IT Unit is still waiting for the delivery of the online system web servers. The Board received the software in September. If the new servers are not delivered and installed within the week, an alternative server will be used.

NABP ELTP Conference Report

Mr. Konstantinov reported that Ms. Banks attended the Electronic Licensure Transfer Program (ELTP) Conference on September 16, 2002. The ELTP was developed in 1996 by NABP as a communication tool for the State Pharmacy Boards. One licensed copy of the program, written in Lotus Notes, a database/email software package, was sent to each Board of Pharmacy, along with personal computer leased by NABP. Information that was previously faxed or mailed to each Board is now available by logging in, downloading attachments and entering information directly into the system, at no cost to the Boards.

Web Site Statistics

Mr. Konstantinov reported the Board's web site statistics for the first quarter of Fiscal Year 2003. A total of 14,842 persons visited the web site and the Board received a total of 535 emails. The first quarter totals compared with FY 2001 have been 50% increase in the number of visitors and 90% increase in the number of emails in this first quarter of FY 2003. The Pharmacy Board received visits from two new places: Mauritius, in South Africa east of Madagascar and Cocos (Keeling) Island, in the Indian Ocean, Australian territory, near Indonesia and Christmas Island.

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A new section has been added to the Board's web site under Consumer News & Information and Links. The page contains information on pain management. It contains links to local and national organizations, and a link to the DHMH Pain Management Committee, who is developing a report on assessment, management and the role of health care practitioners.

Public Relations Report – Joan Lawrence

Board's 100th Year Celebration – Updates

Ms. Lawrence distributed a draft press release statement for the Board's approval.

Board Action

Ms. McCarthy-Hawkins moved for acceptance of the press release. The motion was seconded by Ms. Furman and passed by the Board.

Board Action

Dr. Love moved that the Board close the public session to discuss the responses from the three Wet Lab Examination candidates on June 13, 2002. The motion was seconded by Ms. McCarthy-Hawkins and passed by the Board.

After much discussion and review, Mr. Balch moved to notify the three candidates in question to submit a letter of reference and that the candidates appear before the Board in person. The motion was seconded by Ms. Furman and passed by the Board. Mr. Yee and Ms McCarthy-Hawkins will be recused from the hearing.

Pres. Ades adjourned the Public Session at 11:55 a.m.